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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,485	07/20/2001	Mark B. Lyles	068986.0102	1620

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34-

Office Action Summary

Application No.

09/910,485

Applicant(s)

LYLES, MARK B.

Examiner

Daniel M Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-17,35-40,42,47 and 55-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47 and 55-69 is/are allowed.
- 6) ☒ Claim(s) 5-17,35-40,42 and 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 15 June 2004 in response to the Non-Final Office Action mailed 24 February 2004. Claims 5-17, 35-40, 42, 47 and 55-69 were considered in the 24 February Office Action. Claims 5 and 68 were amended and claims 70-72 were added in the 15 June Paper. Claims 5-17, 35-40, 42, 47 and 55-72 are pending and under consideration.

Response to Amendment

Claim Objections

Objection to claim 68 as informal is withdrawn.

Claim Rejections - 35 USC § 103

Claims 5-17, 35-40 and 42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lubowe (1984) U.S. Patent No. 4,474,763 in view of Li (1996) WO 96/01617.

Response to Arguments

In response to the *prima facie* case of record, Applicant has amended claim 5 such that the nucleic acids applied are limited to having one or more R-group substitutions provided after isolation. Applicant urges that the claims are now distinguished from the cited art because the art fails to teach a method comprising applying a formulation comprising isolated nucleic acids having one or more R-group substitutions provided after isolation.

This argument has been fully considered but is not deemed persuasive. As discussed in previous Office Actions, Li teaches a sunscreen formulation comprising nucleic acids, which, because said nucleic acids are extracted from natural sources, comprise one or more R-group substitutions including methylation (see, *e.g.*, the fourth paragraph on page 4 of the 24 February Office Action). The limitation that the substitution be provided after isolation is a process limitation which must result in a product having materially different properties in order to distinguish the product from the prior art.

In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) states: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”

Absent evidence to the contrary, one of ordinary skill in the art would expect that DNA methylated in a cell would be the same as DNA methylated after isolation. Therefore, the DNA in the formulation of Li is the same as the DNA of the instant claims and the method of the instant claims is obvious over the method of Lubowe in view of Li for reasons of record.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 70-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Li (1996) WO 96/01617 (previously made of record).

The instant claims are directed to a method to reduce the absorption of ultraviolet radiation by the skin of a mammal comprising applying a formulation comprising nucleic acids having one or more R-group substitutions provided after isolation to the skin of the mammal. Claims 71 and 72 further limit the R-group substitutions to being provided by an enzyme or by chemical reactions.

As discussed in previous Office Actions, Li teaches a method to reduce the absorption of ultraviolet radiation by the skin of a mammal comprising applying a sunscreen formulation comprising nucleic acids, which, because said nucleic acids are extracted from natural sources, comprise one or more R-group substitutions including methylation. As discussed above, the limitation that the substitution be provided after isolation is a process limitation which must result in a product having materially different properties in order to distinguish the product from the prior art. Likewise, the limitations of claims 71 and 72 do not distinguish the instant claims from the teachings of Li because, absent evidence to the contrary, one of ordinary skill in the art would expect that DNA methylated in a cell would be the same as DNA methylated after isolation regardless of whether methylation was provided by an enzyme or by a chemical reaction.

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Thus, the formulation comprising isolated nucleic acids having one or more R-group substitutions taught by Li is the same as the formulation of the instant claims. Therefore, the method of Li anticipates the method of the instant claims 70-72.

Allowable Subject Matter

Claims 47 and 55-69 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

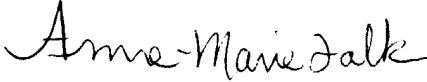
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636